



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2020-N-1338]**

### **Process for Publishing Emergency Use Authorizations for Medical Devices During Coronavirus Disease 2019**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the process for publishing FDA Emergency Use Authorizations (EUAs) for medical devices related to the Coronavirus Disease 2019 (COVID-19) public health emergency. FDA believes that this process will allow the Agency to rapidly publish EUAs that have been issued for medical devices under the Federal Food, Drug, and Cosmetic Act.

**DATES:** This process is effective **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Submit written requests for single copies of an EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the Authorizations.

**FOR FURTHER INFORMATION CONTACT:** Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll free number).

**SUPPLEMENTARY INFORMATION:**

I. Background

Section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, radiological or nuclear agent or agents when there are no adequate, approved, and available alternatives and other criteria are met.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of Health and Human Services (HHS) must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including personnel operating under the authority of Title 10 or Title 50, United States Code, of attack with (i) a biological, chemical, radiological, or nuclear agent or

agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces<sup>1</sup>; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad. Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied.

Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the *Federal Register* a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Additionally, under this provision, the Secretary shall make any revisions to an authorization under section 564 of the FD&C Act available on FDA's website.

## II. Medical Devices for Which the Secretary Has Declared That Circumstances Exist Justifying Their Emergency Use

On February 4, 2020, the Secretary of HHS determined that there is a public health emergency that has a significant potential to affect national security or the health and security of

---

<sup>1</sup> In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

U.S. citizens living abroad, and that involves the SARS-CoV-2. Pursuant to this determination, the Secretary has made the following declarations that circumstances exist justifying the authorization of emergency use of the following products:

- On February 4, 2020, under section 564(b)(1) of the FD&C Act, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus (SARS-CoV-2), subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the *Federal Register* on February 7, 2020 (85 FR 7316).
- On March 2, 2020, under section 564(b)(1) of the FD&C Act, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the declaration of the Secretary was published in the *Federal Register* on March 10, 2020 (85 FR 13907).
- On March 24, 2020, under section 564(b)(1) of the FD&C Act, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products use as medical devices, due to shortages during the COVID-19 outbreak, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the declaration of the Secretary was published in the *Federal Register* on March 27, 2020 (85 FR 17335).

### III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

### IV. Process for Publishing EUAs for Medical Devices During COVID-19

To facilitate publication of each EUA, and each termination or revocation of an EUA under section 564, in accordance with section 564(h)(1) of the FD&C Act, the Agency intends to use the following process:

- Rather than publishing a separate Notice of Availability (NOA) for each COVID-19 related EUA for a medical device, FDA intends to publish periodically a consolidated NOA. This periodic NOA will announce the availability of all the COVID-19 related EUAs for medical devices that issued during the relevant period. The consolidated NOA will provide instructions to the public on how to view the EUAs, and instructions for persons interested in obtaining a copy of the COVID-19 related EUAs.
- COVID-19 related EUAs for medical devices will be accessible on the internet at the FDA webpage entitled “Emergency Use Authorization,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.
- COVID-19 related EUAs for medical devices are also currently accessible on the internet from the FDA webpage entitled “Emergency Use Authorizations,” available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>.

Dated: May 28, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2020-11898 Filed: 6/1/2020 8:45 am; Publication Date: 6/2/2020]